AUG 1 3 2002

510(k) Summary
Ceralas Diode Laser System
(K013691)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.
Date prepared: May 29, 2001

Name of Device and Name/Address of Sponsor

Ceralas D 980 nm Diode Laser System (Model D50)
biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser

Predicate Devices

Ceralas D Diode Laser System
VNUS Medical Technologies' VNUS Closure System
DioMed, Inc.'s 810 nm Surgical Laser and EVLT Procedure Kit Laser

Intended Use/Indication for Use

The Ceralas D 980 nm Diode Lasers are intended for endovascular coagulation of blood vessels. The Ceralas D 980 nm Diode Lasers are indicated for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 60601-1; IEC 601-2-22; and EN 60825-1.

In addition, biolitec performed a single arm, open study at a single site with two clinical investigators to determine the ability of the Ceralas D Laser System to treat

superficial vein reflux of the greater saphenous vein. Ninety-six percent of the patients enrolled in the study achieved complete closure of the vein. All adverse events were of limited duration and resolved completely.

Substantial Equivalence

The Varicose Vein Ceralas D has the same intended use and indications for use as VNUS Medical Technologies' VNUS Closure System and Diomed, Inc.'s 810 nm Surgical Laser and EVLT Procedure Kit laser. In addition, the superficial vein reflux Ceralas D is the exact same device as the cleared Ceralas D. Furthermore, clinical data demonstrate that the superficial vein reflux Ceralas D is substantially equivalent for endovascular coagulation of blood vessels in patients with superficial vein reflux.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Biolitec, Inc.
c/o Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-5910

Re: K013691
Trade/Device Name: Ceralas D 980nm Diode Laser Systems
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 29, 2002
Received: May 29, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 1

Indications for Use Statement

510(k) Number (if known): K013691

Device Name: **Ceralas D Diode Laser System**

In addition to the already cleared indications:

The Ceralas D 980 nm Diode Lasers are indicated for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013691